CUMULATIVE RISK ASSESSMENT GUIDELINES FOR PLANNING AND PROBLEM FORMULATION

EPA Risk Assessment Forum
Cumulative Risk Assessment Technical Panel

Science & Technology Policy Council

January 12, 2022

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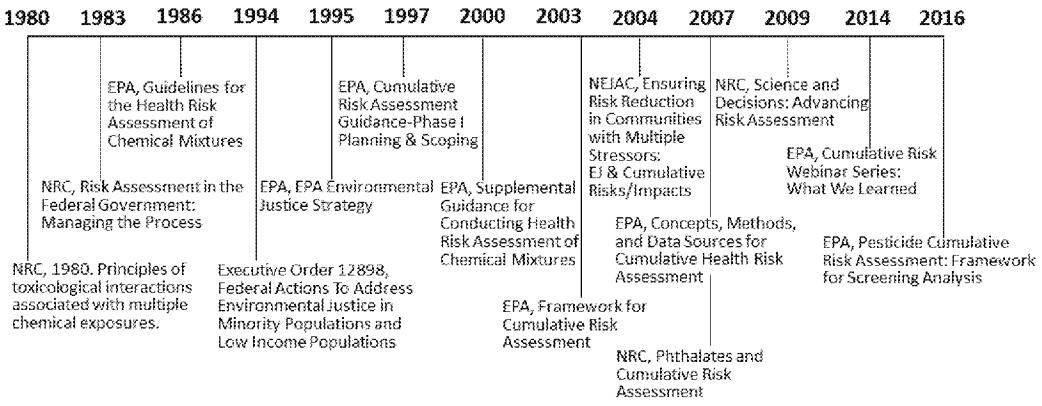
Background & Impetus

- Administrator & Science Policy Council: CRA Planning and Scoping ,1997
- National Environmental Justice Advisory Council: *Ensuring Risk Reduction in Communities with Multiple Stressors,* 2004
- NRC recommendations to EPA
  - *Phthalates CRA,* 2008
  - *Science & Decisions,* 2009
- Federal Statutes
- 140K comments to the CRA Methods Docket, 2013
- Annotated Outline – *CRA Key Elements*, 2014
- New revised STPC charge for CRA Guidelines in 2016

A TIMELINE OF KEY CRA PUBLICATION MILESTONES



Purpose

- Updates 1997 STP Guidance on CRA Planning and Scoping
  - Revises general statements of intent with improved analytic "fit for purpose" strategy for CRA design
  - Provides methods by which stressors are identified and incorporated into problem formulation & conceptual model
  - Replaces required actions with recommended planning steps
  - Adjusts CRA perceptions and clarifies planning steps
  - Refines consideration of how to incorporate non-chemical stressors

Draft Outline

- 1 INTRODUCTION TO CRA GUIDANCE FOR PLANNING AND PROBLEM FORMULATION
  - 1.1 Background and History
  - 1.2 Deciding to Conduct a CRA
  - 1.3 Organization of the Document
- 2 CRA PLANNING AND SCOPING
  - 2.1 Decision Context and Initiating Factors
  - 2.2 CRA Participants and Stakeholder Involvement
  - 2.3 Statement of Purpose
  - 2.4 Scoping CRA Objectives, Constraints, Boundaries
  - 2.5 Tiering and Phasing the Assessment
  - 2.6 Data Quality, Needs, Availability
  - 2.7 Project and Risk Management Considerations
- 3 PROBLEM FORMULATION

Draft Outline (con't.)

- 3 PROBLEM FORMULATION
  - 3.1 Examine Risk Management Options Based on the Initiating Factor
  - 3.2 Conceptual Model
  - 3.3 Consideration of Stressors
  - 3.4 Receptors of Potential Interest
  - 3.5 Exposure-Response Modifiers
  - 3.6 Adverse Effect and Exposure Stressor Groups
  - 3.7 Integration of Data for Examining Stressor-Response Relationship(s)
  - 3.8 Analysis Plan
  - 3.9 Uncertainty and Variability
  - 3.10 Final Steps in CRA Planning and Problem Formulation

Planning Milestones

- 1. Initiating factors (Section 2.1)
- 2. Identification of stakeholders (Section 2.2)
- 3. Statement of purpose (Section 2.3)
- 4. Evaluation of the fit for purpose (Section 2.4)
- 5. Scoping summary statement (Section 2.5)
- 6. Conceptual Model (Section 3.2)
- 7. Weight of evidence evaluation (Section 3.7)
- 8. Analysis plan (Section 3.8)

CRA Planning Guidelines

- Lays the foundation for considering current and future cumulative risk analytical methods
- Are intended for use with other EPA guidelines on methods such as the *Guidelines for Assessment of Chemical Mixtures, and Supplementary Guidance for Assessment of Chemical Mixtures*
- Describes considerations for when CRA is a suitable assessment method
- Provides steps for planning the CRA to meet the need of the risk manager – "*fit for purpose*"

CRA Planning Guidelines

- CRA follows the risk assessment convention of examining toxicological dose-response effects on adverse outcomes from common MoA or key events, or converging adverse outcome pathways
- Multiple stressors can be interpreted broadly to include mixtures, chemicals that share a common MoA or adverse outcome, chemical and nonchemical factors that might interact, or any combination
- Highlights that CRA problem formulation can focus on either the stressor or the receptor
- Guidelines are not prescriptive

CRA Planning Guidelines

- Develops concept of exposure-response modifier as a condition or state (e.g., gender, life stage, socioeconomic status, etc.) affecting the stressors of interest, whereas a stressor is characterized as a physical, chemical, biological, or psychosocial agent of primary concern.
- Discusses design and use of conceptual models
- Provide recommendations for developing a CRA analysis plan
- Advocates tiering and phasing of the analysis to best match resources and level of effort to the risk management decision
- Receptor based problem formulation is of noted value to communities expressing environmental justice concerns
- Responsive to disadvantaged human populations who may be more vulnerable to primary stressors

External Peer Review

- **Panel Review June 28, 2021**
  - Nicole C. Deziel, Ph.D., M.H.S.
  - Amy D. Kyle, Ph.D., M.P.H.
  - Stephen H. Linder, Ph.D.
  - Devon Payne-Sturges, Dr.P.H., M.P.H., M.Engr
- **Seven Charge Questions**
  - Do the CRA guidelines describe an appropriate, "fit for purpose" approach?
  - CRA is contrasted with Cumulative Impact Assessments to highlight the need to match the assessment to the risk management question(s). Is this clear?
  - Are the concepts and scientific/technical considerations described in the section on problem formulation clear?
  - Comment on the recommended approach to incorporate addressing exposure/response modifiers to address vulnerability factors.
  - Are there other CRA concepts or references that should be incorporated?
  - Comment on the use of vulnerable to address sensitive and susceptible.
  - Do the Guidelines address CRA planning processes not well-characterized in other EPA risk guidelines?

External Peer Review

- **Major themes from the external peer review**
  - Wide range of comments from complementary to recommendations for reorganization of the Guidelines.
  - The primary orientation of the reviewers was that the guidelines were too restricted and focused on addressing risk management decisions.
  - Recommended an assessment continuum with CRA occupying a certain position, given its data demands and explicit specifications.
  - Commented that the discussion of conceptual models would benefit from simplifying and an example.
  - Vulnerability is insufficiently sensitive to pejorative interpretations whereby blame is assigned to vulnerable individuals/populations.
  - Reviewers agreed the Guidelines should include a timeline figure and associated narrative describing the history of the development of CRA concepts related to EPA objectives.
  - Recommended that the Guidelines express EPA's core commitment to facilitate and institutionalize mitigation consistent with its regulatory mandates.

Revision and RAF Review

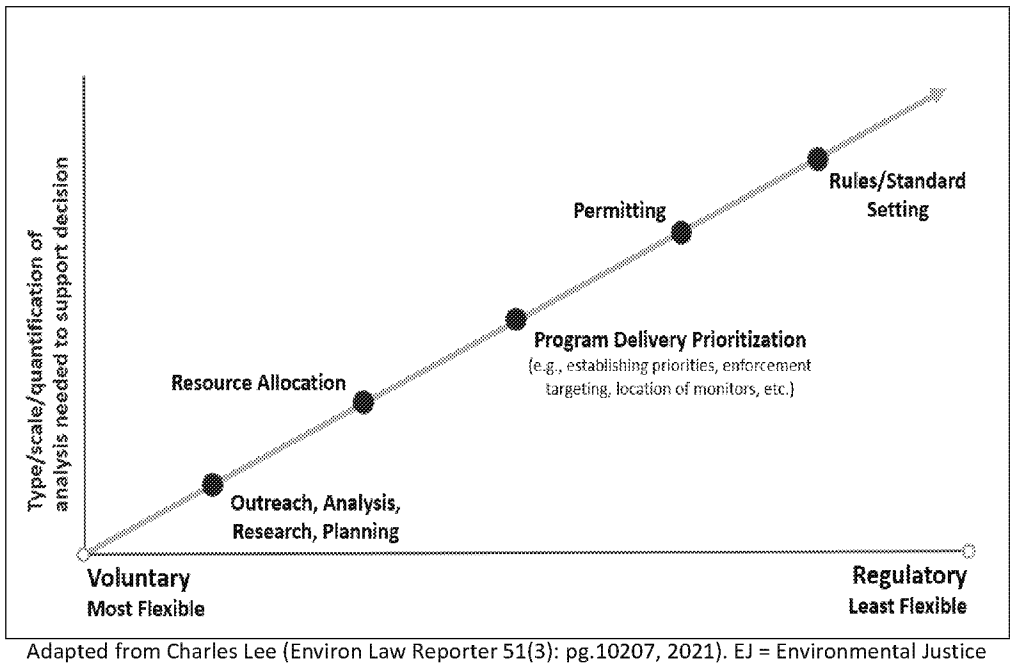
- The CRA Technical Panel reformed 3 writing teams to revise the Guidelines
  - Each team met 5-7 times from September to October
  - The CRA Technical Panel reviewed the revised draft and commented
  - The revised draft was finalized incorporating Technical Panel comment

- The RAF CRA Review Committee was reconvened
  - RAF CRA Review from Nov. 10 to Dec. 19
  - Chair, Ed Ohanian, OW
  - Chris Dockins, OP
  - Kristin Riha, OAR
  - Monique Perron, OPP
  - Rebecca Dzubow, OCHP
  - Carolyn Persoon, R5
  - Michael Breen, ORD
  - Kathryn Gallagher, OW
  - Jason Mills, OLEM

CRA or Impact Assessment?

- The overarching defining factor in deciding to conduct a CRA or impact assessment is the "fit for purpose."
- A primary defining factor in establishing the fit for purpose is the extent to which specific types of uncertainty in causality between stressors and receptors can be tolerated.
- The Cumulative Assessment Continuum illustrates relationship between data analysis, the flexibility to choose data and analysis, and the purpose of the assessment.

Spectrum of EJ Integration Approaches, Using a "Fit-for-Purpose" Continuum



Adapted from Charles Lee (Environ Law Reporter 51(3): pg.10207, 2021). EJ = Environmental Justice